

**Material Code M0993**

**Revision 00**

**Type** HDPE  
**Brand name** HDPE 5502  
**Supplier** TOTAL PETROCHEMICALS

**Sterilization Stability:**

	<u>Compliant</u>	<u>Comments</u>
Gamma Sterilization	YES	25 KGy
Ethylene Oxyde	YES	-

**Biocompatibility Data:**

	<u>Compliant</u>	<u>Standard</u>	<u>Comments</u>
USP Class VI	YES	USP	-
Cytotoxicity	YES	ISO 10993-5	-
Sensitization	YES	ISO 10993-10	-
Irritation or intracutaneous reactivity	YES	ISO 10993-10	-
Systemic toxicity (acute)	YES	ISO 10993-11	-
Hæmocompatibility	YES	ISO 10993-4	-

**Main Regulatory Compliances:**

	<u>Compliant</u>	<u>Comments</u>
BPA	YES	Not used in the manufacturing process
CONEG (Cadmium, chromium, lead and mercury)	YES	Not used in the manufacturing process
Drug Master File	YES	-
Food Contact	YES	-
European Directive 2002/95/EC & 2011/65/UE - RoHS/RoHS2	YES	Not used in the manufacturing process
Latex or Natural Rubber	YES	Not used in the manufacturing process
Phthalates	YES	Not used in the manufacturing process
TSE / BSE	YES	Not used in the manufacturing process
European Directive (EC 1907/2006) REACH	YES	-
SVHC List	YES	Not used in the manufacturing process
MSDS	YES	-

**Technical Characteristics:**

	<u>Value</u>	<u>Measuring Method</u>	<u>Comments</u>
Injection	YES	-	-
Density	0.955 g/cm3	ASTMD 792	-
Melt Flow Rate	0.35 g/10min		-
Tensile Strength at Yield	400 psi	ASTMD 638, Type IV	-
Other mechanical property 1	600 %	D-638, Type IV	Elongation at break
Other mechanical property 2	200000 psi	ASTMD 590	Flexural Modulus

<b>R&amp;D Validation</b>	FRA	<b>QA/RA Validation</b>	CGI
<b>Date</b>	23-11-2017	<b>Date</b>	23-11-2017

Please be aware regarding Medical Applications, Technical Characteristics and Regulatory requirements:

Promeppla Group does not test or analyze this material for any specified regulatory requirements nor for the any technical data. The information provided by the raw material manufacturers has been compiled by Promeppla Group, in a readily retrievable format, as part of our service to you, our customer. Customers and End-Users must themselves determine suitability of use and conduct The Sterilisation Data presented herein, is provided solely for informative purposes only. The Sterilisation stability must be validated by the Customer and/or the End-User. We remain at your disposal should you need any additional information.